STATEMENT OF WORK FOR
PATIENT RECRUITMENT SUPPORT MATERIALS

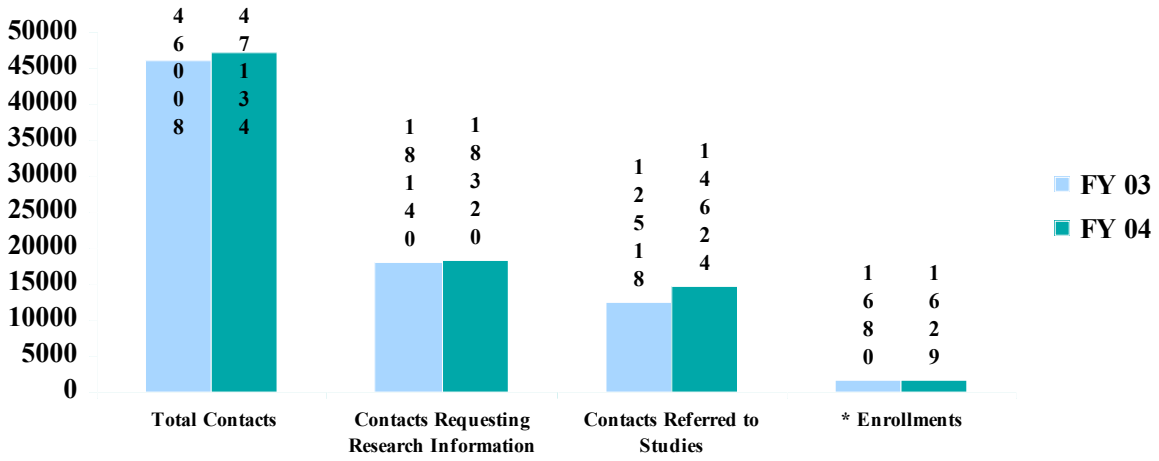
A. INTRODUCTION

The Clinical Center (CC) is the clinical research facility of the National Institutes of Health (NIH) and serves as a premier center for clinical research. It provides patient care, services, training, and the environment in which NIH clinician-scientists translate emerging knowledge into better understanding, detection, treatment, and prevention of human diseases. The CC, through NIH's Intramural Research Program, provides patient support services for the 15 NIH Institutes that admit patients and healthy volunteers for the purpose of participating in the more than 1,000 intramural biomedical research studies that cover a wide spectrum of common and rare diseases. More information about the NIH Clinical Center may be found at http://clinicalcenter.nih.gov.

The CC's Patient Recruitment and Public Liaison Office (PRPL) supports the research mission of NIH by assisting clinician-scientists in the recruitment of patient and healthy volunteers to participate in research protocols, more commonly referred to as medical research studies or protocols. PRPL, opened in the fall of 1996, develops and implements recruitment plans for specific studies conducted at the CC, designs and implements ad campaigns for multiple diseases and disorders, and participates in community outreach events and national conferences. PRPL operates a call center where health-care providers and members of the general public may obtain CC research information, be pre-screened for designated studies and referred to specific studies for further evaluation and enrollment. PRPL's Clinical Research Volunteer Program is responsible for the recruitment and compensation of healthy volunteers who participate as research control subjects in clinical trials. Information specific to each research study may be found on the CC's website at: http://clinicalstudies.info.nih.gov/ and on the NIH-sponsored website: http://clinicaltrials.gov.

Approximately 20% of new patient and healthy volunteers enrolled in CC-based studies come through the PRPL call center. Between 8% -11% of those expressing an interest in clinical research are enrolled in a study.

Table 1. FY03-04 PRPL Program Data.



Qualitative and quantitative evidence illustrates support for clinical research (Research America, 2004) and the public is generally aware that clinical trials are a crucial component in the research, development, and evaluation of disease treatment strategies. However, clinicians and researchers have historically experienced problems in recruiting adequate numbers of individuals to participate in clinical research studies. In fact, patient recruitment is one of the most significant bottlenecks in treatment development. Many patients who would be eligible to participate never have the opportunity to do so, and most potential patients do not know that a clinical trial might be a treatment option for them. Many physicians aren't aware of the clinical trials available to their patients, thereby making it less likely that their patients will participate. In addition, knowledge about the clinical research process varies widely depending on a number of factors including age, gender, socio-economic status, education, and ethnicity. Myths and misconceptions abound about safety and information related to participation in clinical research, particularly among minorities.

Slow or insufficient patient enrollment in clinical trials contributes significantly to the slow rate of completion and occasional failure of some trials (Spilker & Cramer, 1992). In 2000, for example, an estimated 78 percent of all clinical studies failed to enroll the required number of patients on time (Getz, 2000). The costs of failed or delayed trials include wasted resources that were allocated to the research program, the costs of participants' time, and reticence on the part of primary care professionals to refer additional patients.

Recruitment and retention of patients for clinical research at the CC has become more difficult (Gallin and Varmus, 1998). As research teams recruit individuals for CC trials they face additional challenges because unlike major medical centers that rely on an institutional patient-base, affiliated physician networks or medical faculty, the CC must recruit patient and healthy volunteers directly from external sources. In the past, most research volunteers were referred by community physicians. However, the advent of managed care and the increased number of clinical trials being conducted by major

medical centers and pharmaceutical companies have resulted in the need to initiate new strategies to recruit patients.

Individuals participate in research for the following reasons: altruism, unsuccessful medical treatments, compensation, and hope for a cure or improved quality of life, attention, dissatisfaction with care provider. Though no data has been collected to date, it can be asserted that many of those participating in CC early phase clinical trials, which comprise 50% of the CC's research portfolio, do so for altruistic reasons, to improve health status, or to receive free health care. Many healthy volunteers participate in order to receive compensation and/or free medical tests.

It is critical that the public, including health-care providers become well educated and informed about the clinical research process, and the availability of clinical trials at the CC. This can be accomplished, in part, through a variety of print and multimedia materials that are used to reinforce the following **key** messages:

- the NIH Clinical Center is the government's premier clinical research organization
- human participants (subjects) are needed to develop new ways to prevent, diagnose, and treat or cure common and rare diseases
- there is a difference between advancing knowledge through clinical research and clinical practice
- strict safeguards exist to protect research participants (subjects) from undue risk;
- a study may have a direct benefit to the participant or might help researchers find ways to improve health care for future generations

B. GENERAL REQUIREMENT

PRPL is in need of communications materials (Brochures, Videos and DVDs) to complement its recruitment and outreach activities for use with two key audiences:

- diverse members of the lay public
- health-care providers

The contractor shall develop creative concepts, design, format, content, and graphics for all materials. The contractor shall produce these materials per the specific deliverables described below. In addition, at the discretion of NIH the contractor shall be responsible for having the creative concepts and messages focus-group tested by the contractor. The focus group (s) shall be comprised of a diverse group of adults 18 – 65.

C. SPECIFIC REQUIREMENT

The contractor shall develop and present creative concepts including design, key messages, and tag lines in collaboration with the government for the entire set of communication materials (Brochure, Video and DVD). The government shall schedule the initial meeting and three additional meetings to refine and finalize the concepts. Sample focus group questions shall be proposed by the contractor during the fourth meeting with the government.

In addition, a full design mockup exhibit for review and approval by PRPL and CC leadership must be submitted in accordance with the timeframe specified herein.

If requested, the contractor shall market test the creative concepts using focus groups. If requested, the contractor shall also produce the following materials relative to the initial creative research and focus group testing:

- Samples of initial creative concepts including messages and design.
- Focus group questions

The contractor shall develop a minimum of two sample creative concepts for each audience. The contractor shall write and submit a summary report of comments and suggestions made by focus group attendees to the government. Focus groups shall be conducted by the contractor following government approval of the design concepts and focus group questions.

The contractor shall prepare camera-ready files for the brochure to go to production. If requested, the contractor shall have the ability to develop and produce the exhibit, video, and DVD.

The contractor shall ensure that each item (brochure, video, DVD) contains information about;

- the NIH Clinical Center (including location);
- clinical trials (definition) and the importance of participating
- informed consent
- the patient and healthy volunteer referral process
- how to obtain additional information about research studies

Each item must contain NIH and DHHS logos. Upon award, each item must undergo the DHHS clearance process for electronic and print materials. The contractor shall provide the necessary item specifications so PRPL may obtain the necessary DHHS clearance. Each item must be made to be produced in both an English language and a Spanish language version. All of the materials must reflect a consistent “look and feel” to represent a common creative concept(s). Elements in the materials shall reflect some elements contained in the CC home page. Additionally, each item must contain the key

messages and calls to action. Following are examples of potential creative concepts and calls to action although the contractor shall work to develop a novel creative concept.

Potential Creative Concepts:

- NIH, where tomorrow's medicine is practiced today.
- Medical research today for a healthier tomorrow.
- The NIH Clinical Center, where research volunteers
- Help shape tomorrow's medicine.
- Your participation today may lead to tomorrow's cures.
- NIH, A place of hope.

Sample Calls to Action:

- Call toll free for study information
- We're open from x to x for your call
- Speak with your health-care provider to see if clinical research is for you

- 8x10 Exhibit The contractor shall design and produce exhibit panels (4) that are compatible with exhibit hardware (Panel Dimensions: approx. 111in.x 29.5 in., in possession of the PRPL). The 4 panels make up the large exhibits. The English language and the Spanish language panels shall be interchangeable. Any graphics or images must represent, to the greatest extent possible, a diverse population with respect to race, age, ethnicity, socio-economic status. The graphics in the Spanish panel will represent diversity with respect to age, country of origin (PuertoRican, Dominican, Mexican, Central/South American), and gender.

- Table-Top Exhibits The contractor shall design and produce the table-top exhibits. The exhibits will include carrying cases that are suitable for shipping and general transport. The design and format shall be the same as the large exhibit.

- Color Brochure The contractor shall design and format for production a brochure in two versions: one in English language and one in Spanish language. The government shall supply the English language text but the vendor will be responsible for writing the text in the Spanish language. The contractor shall provide all content, text, images and graphics, in camera-ready form to PRPL.

- English-language video/DVD The contractor shall develop and produce an English language color video, maximum length not to exceed 10 minutes. The video must appeal to a diverse audience and have an appropriate health literacy level. The video must be open captioned and digitized to enable placement on the web. The purpose of the video is to educate a diverse public

about the NIH Clinical Center, clinical trials and why people are encouraged to participate. The video may also include patient testimonials, information about medical advances as a result of clinical research. Master tapes shall be delivered to the requestor.

- Spanish-language video/DVD The contractor shall develop and produce a Spanish language color video, maximum length not to exceed 10 minutes. The video must appeal to a diverse audience and have an appropriate health literacy level. The video must have an appropriate Spanish cultural style and approach. The video must be open captioned and digitized to enable placement on the web. The purpose of the video is to educate a diverse public about the NIH Clinical Center, clinical trials and why people are encouraged to participate. The video may also include patient testimonials, information about medical advances as a result of clinical research. Master tapes shall be delivered to the requestor.

The contractor shall submit a monthly progress report to the Project Officer. Reports shall contain a description of: 1) the work that has been completed, 2) work in progress, 3) work to be completed and any problems related to completion of the work. Reports shall be received by the fifth day of the month, beginning one month following contract award and shall reflect all work up to and including the last work day of the previous month.

D. DELIVERABLES

Item	Description	Quantity	Delivery Date
1	Mock Exhibit (Brochure, DVD, Video	1	1 month after award
2	Focus Group Testing	1	2 months after award
3	Brochure (Color)	4	4 months after award
4	Table Top Exhibit (English)	2	5 months after award
5	Table Top Exhibit (Spanish)	1	5 months after award
6	8 x 10 Exhibit (English)	1 set of 4 (color)	5 months after award
7	8 x 10 Exhibit (Spanish)	1 set of 4 (color)	5 months after award
8	English Video/DVD	1	6 months after award
9	Spanish Video/DVD	1	7 months after award

10	English DVD w/ cases	250	8 months after award
11	Spanish DVD w/ cases	100	8 months after award
12	Monthly Progress Report	2	5th day each month

E. EVALUATION CRITERIA

Selection of Offerors

Selection of an offeror for award will be based on an evaluation of proposals against the factors below. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value to the Government.

The acceptability of the technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

The Government reserves the right to award without discussions. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

If the Government intends to conduct discussions prior to awarding a contract-

(1) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is Clinical Center policy to conduct discussions with all offerors in the competitive range, the Clinical Center reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

The evaluation will be based on the demonstrated capabilities of the prospective contractors in relation to the needs of the project as set forth in the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria below.

Written Proposal

Demonstrated knowledge of the mission and organization of the NIH and Clinical Center; the variety and phases of research studies that are conducted by the NIH intramural program at the Clinical Center; the advantages and obstacles associated with recruitment of patient and healthy volunteers (particularly women and minorities) to clinical trials.

Total 20 points

Understanding the Requirements and Technical Approach (analytical approach to achieve project objectives). The proposal shall include a detailed description of the rationale for the approach, concepts, messages, design, development, and production as well as the target completion dates for each of the deliverables.

Total: 25 points

Oral Presentation

The contractor shall give an oral presentation to the technical evaluation panel, government patient and healthy volunteer recruitment staff. The government will schedule a one hour meeting with each vendor who will present, at a minimum, background information about the company's services, overview of proposed approach, design concepts and background information about staff who will work on the project, experience creating exhibits and other materials for healthcare organizations (preferably clinical research) along with work samples that demonstrate the ability to create visually and aesthetically pleasing, compelling design concepts and messages. The work samples should be similar to those requested in this solicitation, that have been developed for other health organizations including those written in Spanish.

The vendor shall present initial creative concepts and ideas regarding the project, including design, format and possible messages for the brochure, exhibit, and video/DVD. **The vendor shall provide to the technical evaluation panel at the time of presentation with a written description of the skills and experience of existing or prospective staff who will work on the project.**

Total 30 points

COST FACTOR - 25 points

Basic Cost/Price Information

The prices offered in each proposal shall be totaled and compared. Points shall be awarded according to the following formula:

$$\frac{\text{Lowest Price}}{\text{Offeror's Price}} \times \text{\# available points (25)} = \text{Cost Points Assigned}$$

It is noted that points are merely a guide for source selection and the mathematical outcome is not necessarily determinative of the awardee.

The Government may accept any item or group of items of an offer, unless the offeror qualifies the offer by specific limitations.

The task order type will be time and materials. As such, the costs for the items below should be based upon estimated direct labor hours at specified fixed hourly rates that include wages, overhead, general and administrative expenses, profit; and Materials at cost, including, if appropriate, material handling costs as part of material costs.

Specifically, contractors shall provide a breakdown of labor hours and other applicable costs to produce each of the line items below.